

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

In Re Iso Ray, Inc. Securities
Litigation

Master File No. CV-15-5046-LRS

**ORDER DENYING MOTION
TO DISMISS, *INTER ALIA***

This document relates to:
All actions

BEFORE THE COURT are Defendants' Motion To Dismiss Amended Complaint For Violation Of The Federal Securities Laws (ECF No. 61), Defendants' Request For Judicial Notice (ECF No. 63), and Plaintiffs' Request For Judicial Notice (ECF No. 67). These motions were heard with oral argument on May 12, 2016.

I. BACKGROUND

This is a putative class action brought by investors pursuant to the Private Securities Litigation Reform Act of 1995 (PSLRA). The Plaintiffs are individuals who purchased common stock of Defendant, IsoRay, Inc., between 8:15 a.m. Eastern Standard Time (EST) on May 20, 2015, and 11:36 a.m. EST on May 21, 2015. Plaintiffs allege that during this period:

Defendants issued a press release that materially misrepresented the findings of a medical journal study concerning IsoRay's cancer treatment. The misleading press release artificially inflated the price of IsoRay stock. When investors and the market subsequently learned that the statements in the Company's

**ORDER DENYING MOTION
TO DISMISS, *INTER ALIA* -**

positive press release completely mischaracterized the study's findings, IsoRay's stock price dropped precipitously, damaging investors who purchased IsoRay stock after issuance of the Company's press release.

(Amended Complaint, ECF No. 55 at Paragraph 3).

The medical journal study referred to above- "Analysis of Stereotactic Radiation vs. Wedge Resection vs. Wedge Resection Plus Cesium-131 Brachytherapy in Early-stage Lung Cancer"- was authored by Bhupesh Parashar, M.D., and published on May 19, 2015 in *Brachytherapy* (hereinafter referred to as "the Study"). The Press Release referred to was issued by Defendant IsoRay, Inc., on May 20, 2015. Plaintiffs allege they learned that the statements in the Press Release mischaracterized the Study's findings because of an article authored by Adam Feuerstein entitled "IsoRay Takes Liberties with Lung Cancer Study Results To Prop Up Drug Price" which was published on May 21 at 11:36 a.m. EST on *The Street.com* website.

Plaintiffs assert causes of action for violation of § 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5, promulgated thereunder, 17 C.F.R. § 240.10b-5, as well as a § 20(a) Exchange Act claim against IsoRay Chief Executive Officer (CEO) Dwight Babcock, 15 U.S.C. §§ 78t(a)-(b).

II. LEGAL STANDARDS

A. 12(b)(6) Standard of Review

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937 (2009) (quoting *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955 (2007)). Where the plaintiff fails to "nudge[] his claims across the line from conceivable to plausible, his complaint must be dismissed." *Twombly*, 550

U.S. at 555, 127 S.Ct. 1955. A claim is facially plausible if the plaintiff has pled “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. 678, 129 S.Ct. 1937. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice.” *Id.* (citing *Twombly*, 550 U.S. at 555, 127 S.Ct. 1955). In other words, the plaintiff must provide grounds for his entitlement to relief that amount to more than labels or conclusions and extend beyond a formulaic recitation of the elements of a cause of action. *Twombly*, 550 U.S. at 545, 127 S.Ct. 1955. In making a Rule 12(b)(6) assessment, the court accepts all facts alleged in the complaint as true, and makes all inferences in the light most favorable to the non-moving party. *Barker v. Riverside County Office of Educ.*, 584 F.3d 821, 824 (9th Cir. 2009)(internal citations omitted).

B. Heightened Pleading Standard for Private Securities Fraud Claims

Securities fraud claims are subject to heightened pleading standards under Fed. R. Civ. P. 9(b) and the PSLRA.

To satisfy Rule 9(b), a claim of fraud must “state with particularity the circumstances constituting fraud.” Fed. R. Civ. P. 9(b). Particularity under Rule 9(b) requires the plaintiff to plead the “who, what, when, where, and how” of the misconduct alleged. *Kearns v. Ford Motor Co.*, 567 F.3d 1120 (9th Cir. 2009).

The PSLRA was enacted to establish uniform and stringent pleading requirements for securities fraud actions and “to put an end to the practice of pleading ‘fraud by hindsight.’” *In re Silicon Graphics*, 183 F.3d 970, 988 (9th Cir. 1999). Pursuant to the PSLRA, a complaint alleging private securities fraud must “plead with particularity both falsity and scienter.” *In re Daou Systems, Inc.*, 411 F.3d 1006, 1014 (9th Cir. 2005)(quoting *Gompper v. VISX*, 298 F.3d 893, 895 (9th Cir. 2002)). A securities fraud complaint must consequently “specify each statement alleged to have been misleading, the reason or reasons why the

statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.” *Id.*, 15 U.S.C. § 78u-4(b)(1). If the complaint does not satisfy these pleading requirements, the court, upon motion by defendant, must dismiss the complaint. 15 U.S.C. § 78u-4(b)(3)(A).

C. Incorporation By Reference and Judicial Notice

As a general rule, a court may consider only the pleadings and properly attached documents on a Rule 12(b)(6) motion. *Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th Cir. 2001). There are two exceptions to this rule.

First, under the “incorporation by reference” doctrine, the court may consider “documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [plaintiff’s] pleading.” *Kniesel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005).

Second, courts may take judicial notice of “matters of public record,” but not of facts that may be “subject to reasonable dispute.” *United States v. Corinthian Colleges*, 655 F.3d 984, 999 (9th Cir. 2011). Specifically, courts “may not, on the basis of evidence outside the Complaint, take judicial notice of facts favorable to Defendants that could be reasonably disputed.” *Id.* This rule applies with equal force in securities cases. *In re Am. Apparel, Inc. S’holder Litig.*, 855 F.Supp.2d 1043, 1062 (C.D. Cal. 2012). Fed. R. Evid. 201(b)(2) provides that the court “may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court’s jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot be reasonably questioned.”

///

///

1 Plaintiffs do not take issue with the documents which Defendants ask be
 2 considered by the court under the “incorporation by reference” doctrine.¹ They do,
 3 however, take issue with Defendants’ request that the court take judicial notice
 4 that an Abstract of the Study (“Analysis of Stereotactic Radiation vs. Wedge
 5 Resection vs. Wedge Resection Plus Cesium-131 Brachytherapy in Early-stage
 6 Lung Cancer”) was available on the *Brachytherapy* journal website on May 19,
 7 2015, and that an Abstract of the Study was available on the ScienceDirect website
 8 on May 19, 2015.² Defendants assert this is beyond reasonable dispute because
 9 the Amended Complaint alleges the Study was published online on May 19, 2015.
 10 (ECF No. 55 at Paragraph 66).

11 Paragraph 86 of Plaintiffs’ Amended Complaint quotes from the Press
 12 Release which IsoRay issued on May 20. The Press Release states: “To review
 13 [the Study] as published online as of May 19, 2015, please follow the link
 14 provided here: [http://www.sciencedirect.com/science/article/pii/](http://www.sciencedirect.com/science/article/pii/S1538472115004559)
 15 [S1538472115004559](http://www.sciencedirect.com/science/article/pii/S1538472115004559).” As Defendants point out, their Exhibit 7, “a copy of an
 16 abstract of the Study published on the ScienceDirect website on May 19, 2015,” is
 17 already incorporated by reference in the Amended Complaint and therefore, can be
 18 considered by the court for the proposition that the Abstract of the Study was
 19 available on the website on May 19, 2015.

20 The court agrees with Defendants that their Exhibit 7, and Exhibit 6
 21 (abstract of the Study published on the *Brachytherapy* website on May 19, 2015),
 22 are subject to judicial notice. There is no dispute that the Abstract, as opposed to
 23 the full text of the Study, was available on these websites on May 19, 2015, free of
 24
 25
 26

27 ¹ Exhibits 1-5 and 8-9 attached to Petroni Declaration, ECF No. 62.

28 ² Exhibits 6 and 7 attached to Petroni Declaration, ECF No. 62.

1 charge.³ In securities fraud actions relying on the fraud-on-the-market
2 presumption, courts may take judicial notice of information posted on publicly
3 available websites for the fact that the information is available to the market.
4 *Makaeff v. Trump Univ., LLC*, 715 F.3d 254, 259 n. 2 (9th Cir. 2013). All that
5 Defendants ask the court to judicially notice is the availability of the Abstract on
6 the websites, not the full text of the Study, which Defendants do not dispute was
7 not available on the websites without payment of a fee in excess of \$30.
8 Furthermore, the court agrees with Defendants that the fact Plaintiffs may dispute
9 the legal significance of Exhibits 6 and 7 as pertains to what Plaintiffs contend is
10 Defendants' "truth-on-the-market" affirmative defense, does not mean those
11 exhibits cannot be judicially noticed by the court. The legal implications of the
12 availability of the Abstract and the Study on the websites is discussed below.
13 Defendants' Request For Judicial Notice (ECF No. 63) is **GRANTED**.

14 Defendants have filed no objection to Plaintiffs' Request For Judicial
15 Notice (ECF No. 67), and therefore, the court takes judicial notice of the
16 documents listed in the Fuks Declaration, ECF No. 68. Exhibits A-D are filings
17 with the Securities and Exchange Commission (SEC). SEC filings are appropriate
18 for judicial notice. *Dreiling v. Am. Exp. Co.*, 458 F.3d 942, 946 (9th Cir. 2006).
19 Exhibit E is a copy of historical stock prices for IsoRay for the period between
20 May19, 2015 and February 12, 2016 which was obtained from Yahoo! Finance. It
21 too can be judicially noticed as IsoRay is a publicly traded company. *In re Finisar*
22 *Corp. Deriv. Litig.*, 542 F.Supp.2d 980, 990 (N.D. Cal. 2008). Plaintiffs' Request
23 For Judicial Notice (ECF No. 67) is **GRANTED**.

24 ///

25 ///

26 _____
27 ³ The "Abstract" is part of the Study, found at the beginning of the Study. It
28 is a brief summary of the Study.

**ORDER DENYING MOTION
TO DISMISS, *INTER ALIA* -**

III. DISCUSSION

Rule 10b-5 provides, in relevant part, that it is unlawful to “make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.” To adequately state a claim under Section 10(b) and Rule 10b-5, a plaintiff must allege facts sufficient to show: “(1) a material misrepresentation or omission by defendant, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation, (5) economic loss, and (6) loss causation. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 131 S.Ct. 1309, 1317 (2011) (quoting *Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157, 128 S.Ct. 761 (2008)).

A. Misrepresentations or Omissions (Falsity)

Plaintiffs must show that Defendants made statements that were “*misleading* as to a material fact.” *Matrixx Initiatives*, 131 S.Ct. at 1318 (quoting *Basic Incorporated, et al. v. Levinson, et al.*, 485 U.S. 224, 238, 108 S.Ct. 978 (1988)) (emphasis in original). A statement is material when there is “a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” *Basic*, 485 U.S. at 231-32, 108 S.Ct. 978.

Where plaintiffs rely on an omissions-based theory of liability, they must demonstrate that defendants possessed a duty to disclose the withheld information. *Id.* at 239, n. 17. The duty to disclose is triggered either by a specific requirement under the relevant regulations or “when necessary to make statements made, in the light of the circumstances under which they are made, not misleading.” *Id.* This requirement is based on the recognition that a statement, though literally accurate, may possess by virtue of the context or manner of its presentation, the ability to

mislead investors. *Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 886 (9th Cir. 2008). Statements must be considered in the context of their total presentation. *Hughes v. Dempsey-Tegeler & Co.*, 534 F.2d 156, 176 (9th Cir. 1976).

Plaintiffs identify six statements in IsoRay's May 20, 2015 Press Release which they assert were false or misleading. (Addendum To Amended Complaint, ECF No. 55).

The first two statements in question (Statements 1 and 2) are: "IsoRay's Cesium-131 Lung Cancer Treatment Reports 96% Success in Local Control [. . .] in Newly Published Report" and "IsoRay's Cesium-131 Lung Cancer Treatment Reports [. . .] 100% Survival At 5 Years In High Risk Patients In Newly Published Report." While these statements are "literally accurate," Plaintiffs contend they are misleading. Plaintiffs allege the statement about local control "omits the fact that the two alternative treatment options examined in the Brachytherapy Journal Study (wedge resection alone or stereotactic body radiation therapy)⁴ demonstrated statistically equivalent rates of local control" and "creates the false and misleading impression that Cesium-131 was found to provide an added benefit as compared to surgery alone or surgery plus full body radiation." Plaintiffs allege the statement about survival rate "omits to disclose that the comparable five year survival rate for patients undergoing surgery alone is 98% - - a clinically meaningless difference of two percentage points" and "omits to disclose that the survival analysis is limited because nearly every patient in the study is censored, meaning lost to follow up." As such, say Plaintiffs, "the statement creates the false and misleading impression that the survival rate after five years is attributable to patients having received Cesium-131 treatment when,

⁴ The three treatment options studied were: 1) wedge resection surgery + Cesium-131 brachytherapy (WR+B); 2) WR surgery alone (WR); and 3) whole body external stereotactic radiation therapy (SBRT).

1 in reality, patients undergoing wedge resection surgery alone fared statistically the
2 same.”

3 Defendants’ response is that “the allegedly omitted information was
4 included or incorporated by reference in the Press Release” by virtue of the Press
5 Release providing a link to the *Brachytherapy* journal Study: “To review the
6 report online as of May 19, 2015, please follow the link provided here:

7 <http://www.sciencedirect.com/science/article/pii/S1538472115004559>.”

8 Defendants note that the Study was published on two websites- Science Direct and
9 Brachytherapy- on May 19, 2015, one day before the Press Release was issued.

10 Therefore, say Defendants, all of the information was disclosed through the Press
11 Release or was otherwise publicly available and furthermore, “it is implausible
12 that the analysts and investors who followed IsoRay and anticipated the release of
13 the Study would fail to read the complete Study when it became available.”

14 Alternatively, Defendants assert that “even if the results of the Study were
15 somehow deemed inaccessible to investors, Plaintiffs’ omission claims would still
16 fail because the Company had no obligation to disclose additional details about the
17 Study.” According to Defendants, “the Press Release focused on the Cesium-131
18 Group’s Study results and neither stated or implied anything about how the other
19 two treatment groups performed, nor how Cesium-131 performed relative to those
20 two groups.” (Emphasis in original).

21 The court disagrees with the assertion that the Press Release “neither stated
22 or implied anything about how the other two treatment groups performed, nor how
23 Cesium-131 performed relative to those two groups.” Immediately below the
24 heading of the Press Release which says “ISORAY’s CESIUM-131 LUNG
25 CANCER TREATMENT REPORTS 96% SUCCESS IN LOCAL CONTROL
26 AND 100% SURVIVAL AT 5 YEARS IN HIGH RISK PATIENTS IN NEWLY
27 PUBLISHED REPORT,” there is a sub-heading which states “Cesium-131’s
28 Outstanding Lung Cancer Results **Take On Other Treatment Forms Including**

1 **Stereotactic Radiation.**” (ECF No. 62-1 at p. 50). (Emphasis added). And the
 2 Press Release identifies the title of the Study- “Analysis of Stereotactic Radiation
 3 vs. Wedge Resection vs. Wedge Resection Plus Cesium-131 Brachytherapy in
 4 Early-stage Lung Cancer”- which itself reveals that the performance of Cesium-
 5 131 was measured against the performance of the two other groups. (*Id.*). That
 6 there was a comparison of performance is further revealed by the following
 7 statements in the Press Release: “The study noted that the survival rate at 5 years
 8 was exceptional for the Cesium-131 group, which included many high risk
 9 patients, and Cesium-131 added no noticeable side effects. Treatment with
 10 Cesium-131 was performed at the time of the surgery as a single treatment, **in**
 11 **contrast to another treatment option, external radiation**, which requires
 12 numerous hospital visits.” (*Id.*) (Emphasis added).

13 The court agrees with Plaintiffs that a reasonable inference is the statement
 14 in the Press Release that “IsoRay’s Cesium-131 Lung Cancer Treatment Reports
 15 96% Success in Local Control [. . .] in Newly Published Report” creates a “false
 16 and misleading impression that Cesium-131 was found to provide an added benefit
 17 as compared to surgery alone or surgery plus full body radiation.” And a
 18 reasonable inference is the statement in the press release that “IsoRay’s Cesium-
 19 131 Lung Cancer Treatment Reports [. . .] 100% Survival At 5 Years In High
 20 Risk Patients In Newly Published Report” creates a “false and misleading
 21 impression that the 100% survival rate after five years is attributable to patients
 22 having received Cesium-131 treatment when, in reality, patients undergoing
 23 wedge resection surgery alone fared statistically the same.”

24 The third statement at issue in the Press Release (Statement 3) is “IsoRay [. .
 25 .] announced the online publication of the first major peer reviewed study showing
 26 **improved results** using IsoRay’s Cesium-131 seeds in the treatment of lung
 27 cancer.” (Emphasis added). A reasonable inference is that this statement too is
 28 false and misleading because it suggests treatment with Cesium-131 is superior to

1 the other treatment options, when in fact the Study reached no such conclusion.
 2 Instead, the Study concluded the approaches of the three studies were “all
 3 excellent treatment options,” noted that Study results could indicate “there is no
 4 benefit of adding brachytherapy [. . .],” and cautioned that conclusions
 5 concerning benefits associated with wedge resection using Cesium-131
 6 brachytherapy would “need[] to be proved in a clinical trial.” (Ex. A to ECF No.
 7 55 at pp. 50 and 54). (Emphasis added).⁵ Defendants contend that “in the context
 8 of the entire Press Release which focuses exclusively on Cesium-131's
 9 performance, the Company was clearly referring to the fact that Cesium 131's
 10 results were an improvement over historical treatment” It is true the Press
 11 Release focuses exclusively on Cesium-131's performance. It is also reasonable to
 12 infer, however, that the Press Release implied that Cesium-131 provided better
 13 results than the other treatment options. Therefore, it cannot be concluded that
 14 the Press Release “was clearly referring to the fact that Cesium-131's results were
 15 an improvement over historical treatment” as opposed to an improvement in
 16 performance compared to the other treatment options.

17 Defendants contend that even if the Press Release stated or implied how the
 18 other two treatment groups performed (WR alone and SBRT), it still did not
 19

20 ⁵ Plaintiffs do not assert that the Study indicates there is “no added benefit”
 21 from WR+B. They assert, as does the Feuerstein article, that there “may” be a
 22 benefit, but as discussed herein, the fact there is only a possible benefit was
 23 omitted from IsoRay’s Press Release. The Study explained the possible benefit as
 24 follows: “Although WR+Cs-131 was equivalent to WR in terms of LC [Local
 25 Control] and DFS [Disease Free Survival] suggesting that there is no benefit of
 26 adding brachytherapy, this may not be the case since brachytherapy was added to
 27 high-risk resections, such as those with suspected close or positive margins”
 28 (ECF No. 55 at p. 54).

1 materially misrepresent or omit information about how WR+B stacked up against
 2 WR alone and against SBRT. With regard to Statement 1, Defendants contend the
 3 Press Release did not misleadingly imply that WR+B conferred “added benefit”
 4 because there was in fact “added benefit.” According to Defendants:

5 The Study raises the possibility of “no benefit” in a prefatory
 6 clause in the first paragraph and spends the remainder of the
 7 paragraph refuting it. [Citation omitted]. The Study states
 8 that while local control rates were equivalent, the authors
 9 expected lower local control rates for WR + B because it
 10 had a higher-risk patient population. [Citation omitted].
 11 In other words, by reaching the same rates with a group of
 12 higher-risk patients, WR + B had overperformed, and the
 13 Study stated that the “likely” driver of that overperformance
 14 was Cesium-131. [Citation omitted]. This is “added benefit.”
 That a clinical trial was needed for definitive proof [citation
 omitted] is irrelevant.

11 Plaintiffs’ repeated claim that the reference to “no benefit”
 12 was the “conclusion” of the Study is simply incorrect. In
 13 the actual conclusion of the Abstract and penultimate
 14 paragraph of the Study, the authors state that they favor
 WR + B over WR for high-risk resections.

(ECF No. 70 at p. 6)(Emphasis in original).

15 While this may be a reasonable interpretation of the results of the Study, the
 16 Press Release made no mention of this and did not endeavor to explain why there
 17 was “added benefit” to WR + B compared to WR alone. Accordingly, a
 18 reasonable inference is that even if there was not a material misrepresentation,
 19 there was still a material omission in the Press Release which precluded investors
 20 from judging for themselves just how much of an “added benefit” there was from
 21 WR + B, and with regard to Statement 3, just how “improved” the results were for
 22 WR+ B in comparison to the other treatment options.

23 The same goes for Statement 2. According to Defendants:

24 Plaintiffs claim that differences in overall survival rates were
 25 not statistically significant but make no attempt to substantiate
 26 the claim- they simply cite the Feuerstein Article. [Citation
 27 omitted]. But nowhere in the Study or the Feuerstein
 28 Article does anyone state that the differences in overall
 survival rates were statistically insignificant. [Citation omitted].
 Parroting a claim made by Feuerstein, Plaintiffs argue
 without explanation that overall survival rates were

“clinically meaningless.” [Citation omitted]. But the Study did not state that the overall survival rates were clinically meaningless. Indeed, if WR + B patients had a 100% survival rate despite being higher-risk or sicker, this **could** be characterized as clinically meaningful. Besides, Plaintiffs neither define “clinically meaningless” nor explain how Feuerstein, who is not a medical professional, is qualified to make determinations regarding what is “clinically meaningless.”

(ECF No. 70 at p. 7)(Underlined emphasis in original; **bolded** emphasis added).

Here again, however, the point is that while the Press Release implied a comparison of the survival rates between WR + B and WR alone, it did not divulge what the survival rate was for WR alone so as to allow investors to draw their own conclusions whether the 100% survival rate for WR+B patients “**could** be characterized as clinically meaningful,” and with regard to Statement 3, whether that was an “improved” result in comparison to the other treatment options. (Emphasis added).

The fourth statement (Statement 4) at issue in the Press Release is a quote from IsoRay CEO Dwight Babcock: “We are extremely excited to have our Cesium-131 isotope seeds and mesh used in the treatment of non-small cell lung cancers with such outstanding patient outcomes.” Defendants assert this constitutes mere opinion which is not actionable under Section 10(b) and furthermore, is too vague to be actionable. According to Defendants, “even if the results were viewed as equivalent across the three treatment options, that alone would be a huge success for the company.” (ECF No. 61 at p. 18, citing Paragraph 51 of Amended Complaint). The problem is that the Press Release does not explain that mere equivalence was considered “outstanding” by CEO Babcock. A reasonable inference is that “outstanding” means superior in relation to the other treatment options. In *Omnicare, Inc. v. Laborers Dist. Council Const. Industry*, ___ U.S. ___, 135 S.Ct. 1318 (2015), the U.S. Supreme Court stated that “if a registration statement omits material facts about the issuer’s inquiry into or knowledge concerning a statement of opinion, and if those facts conflict with what

1 a reasonable investor would take from the statement itself, then § 11's omissions
2 clause creates liability.”⁶ A reasonable inference is that Babcock’s statement
3 omitted material facts about his inquiry into or knowledge concerning his opinion
4 and, as discussed above, those facts (local control rate of WR+B versus other
5 treatment options; survival rate of WR+B versus other treatment options) conflict
6 with what a reasonable investor would take from an opinion that “outstanding
7 patient outcomes” resulted from use of WR+B to treat non-small cell lung cancer.
8 Babcock may have had a “reasonable basis” to believe the results were
9 “outstanding,” but that was arguably not communicated to investors via the Press
10 Release.

11 Babcock’s opinion is not “vague” so as to be inactionable. The Press
12 Release makes apparent that his opinion was “moored” to the objective measures
13 of the Study unlike the “parade of rosy adjectives- unmoored to any objective
14 measures” at issue in *In re CornerStone Propane Partners*, 355 F.Supp.2d 1069,
15 1087 (N.D. Cal. 2005).

16 The fifth statement (Statement 5) in the Press Release at issue is “[t]he study
17 noted that the survival rate at 5 years was **exceptional** for the Cesium-131 group [
18]” (Emphasis added). Defendants contend this was not false or misleading
19 because the “five-year results could not possibly have been any better” and the
20 remainder of the aforementioned sentence is that “the Cesium-131 group . . .
21 included many high risk patients, and Cesium-131 added no noticeable side
22 effects.” This argument is not persuasive because: 1) the Press Release does not
23 mention what the survival rates are for the other treatment options; and 2) does not
24

25 ⁶ § 11(a) of the Securities Act of 1933, 15 U.S.C. § 77k(a), gives a buyer of
26 securities a right of action against an issuer or designated individuals for an untrue
27 statement of material fact or omission of a material fact in a registration statement
28 for a public offering.

1 explain the significance of there being many high risk patients and there being no
2 noticeable side effects as compared to the other treatment groups. The sentence
3 does not say the survival rate was “exceptional” **because** of there being many high
4 risk patients and there being no noticeable side effects. It just says it was
5 “exceptional” without saying anything about the other treatment groups.

6 The sixth statement (Statement 6) at issue in the Press Release concerns the
7 description of the Study as “the first major peer-reviewed study” According
8 to Plaintiffs, “[t]he press release failed to disclose that IsoRay provided funding to
9 the report’s author, Dr. Bhupesh Parashar, in connection with the study itself[,]

10 creating the misleading impression that researchers were affirmatively seeking to
11 study IsoRay’s Cesium-131 brachytherapy seeds.”

12 Defendants assert that even if IsoRay’s funding was not publicly available
13 information, the statement is not misleading because “[t]he fact that a study may
14 have been sponsored does not change the fact that it is a ‘peer-reviewed study,’
15 and a statement regarding who performed the study supports no reasonable
16 inferences who sponsored it.” (Emphasis in original). According to Defendants,
17 the word “first” merely indicates the Study shows improved results for lung cancer
18 and does not imply that researchers were affirmatively seeking to study IsoRay’s
19 Cesium-131, as opposed to being sponsored by IsoRay to perform the research. A
20 reasonable inference, however, is the failure of the Press Release to indicate that
21 IsoRay had funded the research of the principal author of the study caused
22 investors to reasonably believe Dr. Parashar had undertaken the research on his
23 own initiative (“affirmatively seeking to study IsoRay’s Cesium-131”), and had
24 the investors known that IsoRay provided the funding, they may have looked at
25 the results with a more skeptical eye and dug deeper regarding the Study results.
26 In other words, there is a reasonable inference of a material omission in this
27 regard.

28 ///

1 Alternatively, Defendants contend IsoRay's funding was known to investors
2 because "[i]t was disclosed on the same page as the abstract (viewable without
3 signing in or paying any fee) on the Science Direct website that the Press Release
4 cited and thus was incorporated by reference." A similar argument is made with
5 regard to the other material omissions alleged by Plaintiffs: that the link to the
6 website identified in the Press Release cures all ills and information pertaining to
7 the Study was otherwise publicly available.⁷ Citing *Noble Asset Management v.*
8 *Allos Therapeutics, Inc.*, 2005 WL 4161977 (D. Colo. 2005), Defendants assert
9 they are not in need of a "truth-on-the-market affirmative defense" because the
10 Study was already public information when they issued their Press Release on
11 May 20, 2015. In the *Noble* case, the district court found the defendants there did
12 not engage in fraud by failing to tell investors about the Food and Drug
13 Administrations's published regulatory guidelines and how they might affect the
14 FDA's view of defendants' application for FDA approval of its drug product. This
15 was because the information was already available to the investors. 2005 WL
16 4161977 at *7. The regulatory guidelines at issue were published in September
17 1998 (63 Fed. Reg. 49583-01), four and a half years before defendants issued a
18 press release in May 2003 which the plaintiff alleged falsely portrayed the results
19 of clinical trials and created a perception in the stock market that the FDA would
20 approve the drug in the near future.

21 The situation is quite different in the case at bar. The Study was issued on
22

23 ⁷ For example, Defendants note that IsoRay investors were aware that the
24 company regularly sponsored Cesium-131 studies, citing Paragraphs 32-33 of the
25 Amended Complaint, and that "[c]ertain details of the Study were also publicly
26 discussed at the May 8, 2015 Advances in Brachytherapy symposium, which the
27 Company discussed in a May 11, 2015 press release," citing Paragraphs 57-59 of
28 the Amended Complaint.

1 May 19, 2015, and one day later the Defendants issued their Press Release. The
2 fraud-on-the-market theory alleged by Plaintiffs is based on the premise that
3 publicly available information is reflected in the market price. *Basic*, 485 U.S. at
4 224. Plaintiffs' allegations regarding the fluctuations in IsoRay's stock price
5 between May 19 and May 21, 2015, raise a reasonable inference that not enough
6 time elapsed between issuance of the Study on May 19 and issuance of the Press
7 Release on May 20 for the results of the Study to be reflected in the market price
8 of IsoRay stock on May 20 after issuance of the Press Release. On May 19,
9 IsoRay stock closed at \$1.62 per share, "virtually unchanged from the prior day's
10 closing price." (ECF No. 55 at Paragraph 84). By the end of trading on May 20,
11 after issuance of the Press Release, the share price was \$3.12, 92% higher than the
12 previous day, (*Id.* at Paragraph 92), and approximately 48.356 million shares had
13 been traded, representing almost 35 times the volume of shares traded the previous
14 day (*Id.* at Paragraph 89). On the morning of May 21, the share price rose to a
15 high of \$3.79 per share. (*Id.* at Paragraph 93). However, after Feuerstein
16 published his article on May 21, the share price plummeted to \$2.01 by the end of
17 trading on that day, (*Id.* at Paragraph 99), and total volume of shares traded on
18 that day was 52.116 million, over 37 times the volume on May 19. (*Id.* at
19 Paragraph 100). Within several days of the publication of this article, IsoRay
20 stock returned to its trading levels prior to May 20 and has traded at those levels
21 ever since. (*Id.* at Paragraph 101).

22 Plaintiffs' Amended Complaint gives rise to a reasonable inference that
23 Defendants find themselves in a position where they are in fact asserting a "truth-
24 on-the-market" affirmative defense. Such a defense excuses a defendant's failure
25 to disclose material information where the information was made credibly
26 available to the market by other sources. *In re Convergent Tech. Sec. Litig.*, 948
27 ///
28 ///

**ORDER DENYING MOTION
TO DISMISS, *INTER ALIA* -**

1 F.2d 507, 513 (9th Cir. 1991).⁸ To avoid liability under this theory, however, “any
 2 material information which insiders fail to disclose must be transmitted to the
 3 public with a degree of intensity and credibility sufficient to effectively counter-
 4 balance any misleading impression created by the insiders’ one-sided
 5 representations.” *In re Apple Computer Securities Litigation*, 886 F.2d 1109,
 6 1116 (9th Cir. 1989). “As a general rule, the truth-on-the-market defense is
 7 intensely specific, so courts rarely dismiss a complaint on this basis.” *In re Amgen*
 8 *Inc. Securities Litigation*, 544 F.Supp.2d 1009, 1025 (C.D. Cal. 2008).

9 Defendants bear a “heavy burden” of proving that information withheld or
 10 misrepresented was transmitted to the public with a degree of intensity and
 11 credibility to effectively counterbalance the misleading impressions created by
 12 insider one-sided representations. *Provenz v. Miller*, 102 F.3d 1478, 1492-93 (9th
 13 Cir. 1996). Therefore, “[a]ny conflicting interpretation of the false or misleading
 14 statements . . . will likely lead to consideration of facts that are inappropriate at the
 15 12(b)(6) stage of the litigation.” *Nguyen v. Radiant Pharm. Corp.*, 2011 WL
 16 5041959 at *7 (C.D. Cal. 2011).

17 It is debatable whether as of the date of the Press Release (May 20), the
 18 Study, released on May 19, had been transmitted to the investing public with the
 19

20 ⁸ The “truth-on-the-market affirmative defense” is a corollary doctrine to
 21 the “fraud-on-the-market” theory. The “fraud-on-the-market” theory is that an
 22 established market assimilates all of the available information regarding a
 23 particular stock and sets the stock price accordingly. Investors make their
 24 decisions in reliance upon the integrity of an informed market and where material
 25 misrepresentations have been placed into the mix of information or omissions
 26 render the market information misleading, the stock price is skewed and investors
 27 may be defrauded. If at the relevant time, the market contained countervailing
 28 information, it is less likely or not likely that the market was defrauded.

1 same degree of intensity and credibility as the Press Release. Although the Press
2 Release provided a link to the Study, the Study could not be accessed without the
3 payment of a \$35.95 subscription fee (Ex. 7 at ECF No. 62-1).⁹ Defendants point
4 out that the Abstract was available free of charge and disclosed the local control
5 and overall survival rates for the “other arms” of the Study (WR alone and SBRT),
6 but there is a legitimate question whether its availability could be deemed
7 sufficient without the Study itself.¹⁰ This is so even if one ignores the rapidity
8 with which the Press Release was issued on the heels of the issuance of the Study
9 and how that factors into the question of whether within the narrow period of time
10 between May 19 and 20, the Abstract could be deemed to have been transmitted to
11 the investing public with the same degree of intensity and credibility as the Press
12 Release.

13 Defendants contend “it is implausible that the analysts and investors who
14 followed IsoRay and anticipated the release of the Study would fail to read the
15 complete Study when it became available.” The court is not persuaded it is
16 implausible. A reasonable investor might well have relied on the May 20 Press
17

18 ⁹ This was a link to the ScienceDirect website. As of May 19, 2015, the
19 Study could also be accessed on the *Brachytherapy* journal website for a fee of
20 \$31.50, although here too, the Abstract could be accessed free of charge. (Ex. 6 at
21 ECF No. 62-1).

22 ¹⁰ For example, the Abstract obviously does not contain the same level of
23 detail as the Study explaining the possible benefit of WR+B to patients deemed
24 “high risk,” even though the Abstract concludes that “[f]or high risk [Wedge
25 Resections], we favor use of Cesium-131 brachytherapy,” notwithstanding that it
26 also concludes “WR, WR+Cs-131, or SBRT are all excellent treatment options for
27 patients with early stage non-small cell lung cancer that are not candidates for
28 lobectomy.” (ECF No. 62-1 at p. 48).

1 Release considering the nature of the information contained in the Study and the
2 fact that payment was required to fully access the Study. A reasonable inference is
3 that this was borne out by the manner in which the market reacted before and after
4 issuance of the Press Release: (1) issuance of the Study on May 19- no reaction; 2)
5 issuance of the Press Release on May 20- stock price leaped to record highs; and
6 3) publication of the Feuerstein article on May 21- stock eventually returned to
7 pre-Press Release levels. Finally, as Plaintiffs point out, a reasonable inference is
8 Defendants issued the Press Release because they knew a reasonable investor
9 would rely on it and would not access the Study itself.¹¹

10 Defendants assert that had they disclosed the information Plaintiffs claim
11 was improperly omitted, it would have made the Press Release misleading.
12 Defendants say it was prudent to refrain from making comparisons between
13 groups because the Cesium-131 group included high risk patients; patient
14 selection bias may have contributed to lower survival in the SBRT group; and
15 apparent equivalence between the Cesium-131 and WR alone groups was
16 discounted because Cesium-131 was used in high risk surgeries. As discussed
17 above, however, the fact is Defendants went ahead and, if not explicitly, at least
18 impliedly compared the groups in terms of relative treatment success. Defendants
19 could have chosen to say nothing, but because they went ahead and said something
20

21 ¹¹ Plaintiffs contend the Study was too complex for a reasonable investor to
22 understand and that is another reason investors relied on IsoRay's Press Release.
23 Defendants note that Feuerstein, who is not a medical professional, was able to
24 understand the Study results soon after their release. Complexity may be an issue,
25 but the more significant issue is accessibility to the Study results within a short
26 window of time. The relative complexity of those Study results may make even
27 more significant the short period of time between issuance of the Study results and
28 issuance of the Press Release.

1 in a Press Release, they were obliged to make fully accurate disclosures about the
2 Study results.

3 A statement is material when there is “a substantial likelihood that the
4 disclosure of the omitted fact would have been viewed by the reasonable investor
5 as having significantly altered the ‘total mix’ of information made available.”
6 *Basic*, 485 U.S. at 231-32. For the reasons set forth above, the court finds the
7 allegations of the Amended Complaint give rise to a reasonable inference of a
8 substantial likelihood that the Study results omitted from the Press Release would
9 have been viewed by reasonable investors as having significantly altered the “total
10 mix” of information made available.

11 12 **B. Scienter**

13 The PSLRA requires a complaint “state with particularity facts giving rise to
14 a strong inference that the defendant acted with the required state of mind.” 15
15 U.S.C. § 78u-4(b)(2)(A). To satisfy this state of mind element, the “complaint
16 must allege that the defendant made false or misleading statements either
17 intentionally or with deliberate recklessness.” *In re VeriFone Holdings, Inc. v.*
18 *Sec. Litig.*, 704 F.3d 694 (9th Cir. 2012)(quoting *Zucco Partners, LLC v. Digimarc*
19 *Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)). A plaintiff must show that a defendant
20 engaged in knowing or intentional conduct. *South Ferry LP, No. 2 v. Killinger*,
21 542 F.3d 776, 784 (9th Cir. 2008). While facts showing a motive and opportunity
22 to commit fraud “provide some reasonable inference of intent,” they are “not
23 sufficient to establish a strong inference of deliberate recklessness.” *In re*
24 *VeriFone*, 704 F.3d at 701. The allegations are to be reviewed “holistically” in
25 determining whether scienter has been adequately pled. *Id.* (quoting *Matrixx*, 131
26 S.Ct. at 1324). “[E]ven ‘[v]ague or ambiguous allegations are now properly
27 considered as a part of a holistic review when considering whether the complaint
28 raises a strong inference of scienter.’” *Zucco Partners*, 552 F.3d at 1006 (quoting

1 *South Ferry*, 542 F.3d at 784). The inquiry “is whether all of the facts alleged,
 2 taken collectively, give rise to a strong inference of scienter, not whether any
 3 individual allegation, scrutinized in isolation, meets that standard.” *Tellabs, Inc.*
 4 *v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310, 127 S.Ct. 2499 (2007). “A
 5 complaint will survive . . . only if a reasonable person would deem the inference of
 6 scienter cogent and at least as compelling as any opposing inference one could
 7 draw from the facts alleged.” *Id.* at 324.

8 With respect to the element of scienter, there is what is known as the “core-
 9 operations inference” regarding the role of key officers of the company:

10 Allegations regarding management’s role may help satisfy
 11 the PSLRA scienter requirement in three circumstances. First,
 12 the allegations may be viewed holistically, along with other
 13 allegations in the complaint, to raise a strong inference of
 14 scienter under the *Tellabs* standard. Second, the allegations
 15 may independently satisfy the PSLRA where they are
 16 particular and suggest that defendants had actual access to
 the disputed information. . . . Third, in rare circumstances,
 such allegations may be sufficient, without accompanying
 particularized allegations, where the nature of the relevant
 fact is of such prominence that it would be “absurd” to
 suggest that management was without knowledge of the matter.

17 *Reese v. Malone*, 747 F.3d 557, 575-76 (9th Cir. 2014).

18 Plaintiffs contend there is no reasonable dispute that Defendants knew the
 19 complete results of the Study and therefore, the fact they published statements
 20 which are inaccurate or misleadingly incomplete is evidence of scienter.
 21 Alternatively, if Defendants did not know the complete results of the Study at the
 22 time they issued the Press Release, Plaintiffs contend that itself amounts to
 23 deliberate recklessness. Defendants do not dispute they (the company and CEO
 24 Babcock) knew the complete results of the Study at the time the Press Release was
 25 issued, but contend that for a variety of reasons, there is not a strong inference of
 26 scienter from the allegations in the Amended Complaint.

27 Defendants note Plaintiffs fail to allege that CEO Babcock had any plans to
 28 exercise his stock options, that he actually exercised his options, that he had plans

1 to sell his stock, or that he actually sold any such stock in order to profit from the
2 alleged fraud. Plaintiffs' response is that the fact Defendants were deprived of the
3 opportunity to profit from their fraud does not negate an inference of scienter.
4 Plaintiffs quote from *Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270
5 F.3d 645, 662 (8th Cir. 2001): "The ultimate profitability of a course of conduct is
6 not conclusive of intent. Just as we cannot countenance pleading fraud by
7 hindsight, neither can we infer innocence by hindsight because the alleged
8 misdeeds did not pay off." Plaintiffs further note there is case law that a fraud
9 complaint need not allege motive. *Tellabs*, 551 U.S. at 325 (although personal
10 financial gain can "weigh heavily" in favor of a scienter inference, the "absence of
11 a motive allegation is not fatal"); *Bruce v. Suntech Power Holdings Co. Ltd.*, 64
12 F.Supp.3d 1365, 1374 (N.D. Cal. 2014)("[f]or plaintiffs' fraud claim to go
13 forward, the SAC need not alleged that Shi had some pecuniary motive for making
14 the challenged statements").

15 According to Plaintiffs, Defendants' argument that the lack of insider stock
16 sales rebuts Plaintiffs' scienter allegations "only makes sense when defendants are
17 aware of the timing of the corrective disclosure," which they were not in this
18 instance. Here, say Plaintiffs, "Defendants had no advance notice of
19 *TheStreet.com* article, and therefore, it is unsurprising that they did not dump their
20 shares before the report was released."

21 Plaintiffs acknowledge that generic profit motive is insufficient to allege
22 scienter, but assert that "IsoRay's financial condition coupled with its attempt to
23 raise funds in wake of the false statements is yet another factor that supports an

24 ///

25 ///

26 ///

27 ///

28 ///

**ORDER DENYING MOTION
TO DISMISS, *INTER ALIA* -**

1 inference of scienter.”¹² Plaintiffs note that in August 2015, IsoRay filed a Form
2 S-3 indicating it intended to offer \$20 million of its stock, and also note that
3 IsoRay’s sales and stock price have been flat for some time. Defendants’ response
4 is that Plaintiffs “do not (and cannot) allege that the Company had an active
5 registration as of May 2015, the only time Defendants could reasonably expect to
6 benefit from their supposed fraud.” Furthermore, Defendants contend there is no
7 allegation that IsoRay was in such dire straits that it needed an immediate infusion
8 of capital to stay in business. On the other hand, there is no dispute regarding the
9 meteoric rise of IsoRay’s stock price upon issuance of the Press Release and its
10 corresponding decline once the Feuerstein article was published. This gives
11 credence to Plaintiffs’ allegation regarding IsoRay’s dependency on positive
12 Cesium-131 study results to raise capital and adds heft to Plaintiffs’ assertion that
13 “IsoRay’s financial condition coupled with its attempt to raise funds in wake of
14 the false statements is yet another factor that supports an inference of scienter.”

15 Defendants note the Amended Complaint “is devoid of a single allegation
16 from a confidential witness . . . or a single internal document that purports to show
17 Defendants’ state of mind at the time the challenged statements were made.”
18 Plaintiffs point out that under the PSLRA, discovery is stayed pending any motion
19 to dismiss, 15 U.S.C. § 78u-4(b)(3)(B), and that lack of confidential witness
20 allegations does not undercut an inference of scienter.

21 Defendants contend that most significantly, “any inference of scienter is
22 negated by the fact that the Company included a link to the public Study in its
23 May 20, 2015 Press Release so investors could easily access and read it for
24

25 ¹² Paragraphs 36-40 of the Amended Complaint allege that IsoRay’s stock
26 price relies on positive Cesium-131 study results. See also Paragraphs 45-56
27 discussing reliance on positive Cesium-131 study results regarding treatment of
28 non-small cell lung cancer to increase stock price and raise capital.

1 themselves.” Defendants say if they “truly intended to mislead investors about the
2 Study’s findings, they would not have pointed investors to the ‘truth’ in the very
3 Press Release allegedly designed to mislead.” This goes back to the “truth-on-the-
4 market” affirmative defense. As discussed above, that is a defense which cannot
5 be resolved on a 12(b)(6) motion to dismiss and needs to be resolved on a motion
6 for summary judgment or at trial.

7 Defendants rely heavily on *In re Rigel Pharmaceuticals, Inc. Securities*
8 *Litigation*, 697 F.3d 869 (9th Cir. 2012), in which the circuit affirmed the district
9 court’s dismissal of a class action complaint alleging securities fraud. The circuit
10 agreed that scienter had not been adequately pled, in part, because:

11 [I]f the individual defendants were acting based on their
12 belief that they had a financial motive to conceal the “true”
13 results of the clinical trial, they would not have voluntarily
14 publicly disclosed all the data and the statistical methodology.
15 They also would not have decided that the people to receive
that detailed information should be the people most likely to
identify any problems with the study- the doctors and the
scientists who were at the scientific meeting and who were
publishing and reading the journal article.

16 *Id.* at 885.

17 *Rigel* is factually distinct from the case at bar in a number of critical
18 respects. In *Rigel*, the plaintiff brought the action individually and on behalf of all
19 other persons who purchased or otherwise acquired the common stock of Rigel
20 Pharmaceuticals between December 13, 2007 and February 3, 2009, a class period
21 of approximately 14 months. This is in contrast to the class period of 27 hours at
22 issue here. The statements in *Rigel* were made in a press release dated December
23 13, 2007, during a conference call of the same date, during a July 8, 2008
24 conference, during a presentation to physicians at an annual scientific meeting on
25 October 27, 2008, and when a scholarly article was published in a medical journal
26 in November 2008. “All the data and the statistical methodology” were disclosed
27 to the doctors and scientists no later than November 2008. The district court also
28 found, and the Ninth Circuit affirmed, that as a threshold matter, the plaintiff

1 failed to adequately plead that defendants had made any false or misleading
2 statements in the press release and during any of the conferences or meetings. *Id.*
3 at 877-882.

4 For the reasons set forth above, the Plaintiffs here have adequately pled that
5 there were false or misleading statements in the May 20 Press Release issued only
6 one day after the Study was published. It is reasonable to infer that this Press
7 Release was aimed primarily at investors who were inclined to rely on it rather
8 than paying a \$30 plus dollar subscription fee to dig into the dense and technical
9 Study itself.¹³ As Plaintiffs point out, while *Rigel* involved an alleged distortion of
10 statistical methodology, the case at bar involves an alleged distortion of results. A
11 reasonable inference is that Defendants put the link to the Study in their Press
12 Release knowing that investors would be unlikely to read the Study before
13 purchasing IsoRay stock.

14 Defendants assert that “[w]hen Plaintiffs’ allegations are considered as a
15 whole, the stronger inference is that Defendants intended to tout their Cesium-131
16 seeds’ success at treating lung cancer, not to compare it to other treatments.”
17 Defendants contend the stronger inference is that “they acted innocently, or even
18 negligently” and that this “is far more compelling than the inference that they
19 engaged in a deceitful, self-defeating, 27-hour fraud that profited no one.” The
20 court disagrees. It concludes that Plaintiffs’ allegations, viewed holistically, give
21 rise to an equally cogent and compelling inference that Defendants acted with
22 “deliberate recklessness” in issuing their May 20 Press Release. Plaintiffs’
23 Amended Complaint alleges “highly unreasonable omission[s]” in the Press
24 Release, “involving not merely simple, or even inexcusable negligence, but an
25 extreme departure from the ordinary standards of ordinary care, and which
26

27 ¹³ Defendants’ description of access to the Study being “easy” is a matter of
28 debate considering the subscription fee.

1 presents a danger of misleading buyers or sellers that is known to the defendant or
2 is so obvious that the actor must have been aware of it.” *In re Silicon Graphics ,*
3 *Inc., Sec. Litig.*, 183 F.3d at 976. There is an equally cogent and compelling
4 inference that in their Press Release, Defendants intended to tout the success of
5 Cesium-131 in treating lung cancer by comparing it to other treatments, but in
6 doing so, recklessly omitted information by which an informed comparison could
7 be made. The Press Release did not qualify any of its statements about the
8 performance of WR+B, while the Study clearly did so.

9 Because a “holistic” review of the allegations in the Amended Complaint
10 raises a strong inference of scienter, Plaintiffs do not need to rely on the “core
11 operations inference.” If they needed to, however, that inference would be
12 available to them and would preclude 12(b)(6) dismissal. A complaint “will
13 usually fall short of the PSLRA standard” where it “relies on allegations that
14 management had an important role in the company but does not contain additional
15 detailed allegations about the defendants’ actual exposure to information.” *South*
16 *Ferry*, 542 F.3d at 784. Reliance on the core operations inference must be
17 accompanied, for example, by “specific allegations about management’s exposure
18 to factual information within the company,” such as their actual monitoring of the
19 data that was the subject of the fraud claim or detailed statements showing
20 defendants’ actual knowledge. *Id.* at 785. The Amended Complaint contains such
21 allegations with regard to CEO Babcock: that he monitored the data that is the
22 subject of the fraud claim (the Study results) and made detailed statements

23 ///

24 ///

25 ///

26 ///

27 ///

28 ///

**ORDER DENYING MOTION
TO DISMISS, *INTER ALIA* -**

1 showing his actual knowledge of that data. (See Paragraphs 12-17; 46-48¹⁴; 58,
2 64¹⁵ and 86¹⁶).

3 Alternatively, this may well be a “rare circumstance” where particularized
4 allegations are unnecessary because it would be “absurd” to suggest Babcock was
5 without such knowledge. As Plaintiffs note, “[t]he success of C-131 is critical to
6 IsoRay’s success and was the only product under development by the Company.”
7 Therefore, as Plaintiffs contend, “[t]he notion that Babcock, who frequently
8 commented on C-131 and was running a company entirely devoted to C-131, did
9 not appreciate the import of the actual results of the Study . . . is absurd.”
10

11 **C. Loss Causation**

12 To recover for securities fraud under Section 10(b) and Rule 10b-5, a
13 plaintiff must establish “‘loss causation,’ i.e., a causal connection between the
14

15 ¹⁴ Paragraph 46 alleges that in a September 30, 2014 Company press
16 release, Babcock observed that “recently released peer reviewed publications
17 reporting positively on Cesium-131 in the treatment of cancer have continued to
18 provide proof and evidence of our product’s effectiveness as reported by industry
19 leaders within the medical field.” Paragraph 47 alleges that Defendant Babcock
20 “touted previously published studies and noted the importance of forthcoming
21 studies as a means to increase the Company’s product use.”

22 ¹⁵ Paragraph 64 alleges that despite flat sales, IsoRay continued to tout
23 forthcoming studies as the key to the Company’s success and cites to a May 18,
24 2015 Maxim Group equity research note which indicated they had spoken to
25 Babcock “who sounded encouraged by the clinical data and number of post-
26 marketing studies that should help drive adoption in the future.”

27 ¹⁶ Paragraph 86 refers to the May 20, 2015 Press Release which contains
28 two quotes from Babcock regarding the Study results.

material misrepresentation and the loss.” *Dura Pharms, Inc. v. Broudo*, 544 U.S. 336, 342, 125 S.Ct. 1627, 1631 (2005). This element can be proven by showing that a corrective disclosure caused the stock price to decline. *Metzler Inv. v. GMBH v. Corinthian Colls, Inc.*, 540 F.3d 1049, 1063 (9th Cir. 2008). A “corrective disclosure” is a disclosure that reveals the fraud, or at least some aspect of the fraud, to the market. *In re Novatel Wireless Sec. Litig.*, 830 F.Supp.2d 996, 1019 (S.D. Cal. 2011). This requirement insures that the market actually learns of and reacts to the specific fraud alleged by the plaintiff, as opposed to reacting to reports of the defendant’s poor financial health generally. *In re Daou Sys., Inc.*, 411 F.3d 1006, 1025-27 (9th Cir. 2005). Loss causation “is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss.” *In re Gilead Sciences Securities Litigation*, 536 F.3d 1049, 1057 (9th Cir. 2008). “So long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate.” *Id.* “This is not a probability requirement . . . it simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of loss causation.” *Id.*

The Amended Complaint alleges facts, taken as true, which establish loss causation, namely that the “corrective disclosure,” the Feuerstein article, revealed the alleged fraud to the market which reacted to it by sending IsoRay’s stock price plummeting after its meteoric rise following IsoRay’s May 20, 2015 Press release. (Paragraphs 95-101; 112-114). As discussed above, the Amended Complaint alleges with sufficient specificity that the Feuerstein article, published on May 21, contained information about the Study which was not already known to the market and which did not merely confirm, characterize or interpret information already known to the market. Although the Study was publicly available prior to May 21, it had only been available since May 19. A reasonable inference is that it had not been communicated with the same intensity and credibility as IsoRay’s May 20 Press Release and therefore, investors failed to appreciate the significance of the

1 information it contained about the results of the other treatment options vis-a-vis
2 brachytherapy (WR+B). *In re Apollo Grp., Inc. Sec. Litig.*, 2010 WL 5927988 at
3 *1 (9th Cir. 2010). While Feuerstein did not disclose anything new that was not
4 already contained in the Study, he provided facts which were missing from
5 IsoRay's Press Release which had been communicated to investors with seemingly
6 much greater intensity and credibility than the Study itself.

8 **IV. CONCLUSION**

9 The Amended Complaint adequately alleges against Defendant IsoRay a
10 primary violation under Section 10(b) of the Exchange Act. Because Defendants
11 do not take issue with Defendant CEO Babcock being a "controlling person" as to
12 IsoRay, the claim against him under Section 20(a) of the Exchange Act will also
13 proceed due to the sufficiency of the allegations of a primary violation. *Howard v.*
14 *Everex Sys.*, 228 F.3d 1057, 1065 (9th Cir. 2000). Defendants' Motion To Dismiss
15 (ECF No. 61) is **DENIED**. This matter shall be set for a telephonic scheduling
16 conference.

17 **IT IS SO ORDERED.** The District Executive shall forward a copy of this
18 order to counsel of record.

19 **DATED** this 1st day of June, 2016.

21 *s/Lonny R. Suko*

22 _____
23 LONNY R. SUKO
24 Senior United States District Judge